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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,471

10/13/2006

Hiroyuki Aburatani

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EXAMINER

NATARAJAN, MEERA

ART UNIT

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1643

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,471	Applicant(s) ABURATANI ET AL.	
	Examiner MEERA NATARAJAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments/arguments in the reply filed on 04/13/2009 is acknowledged and entered into the record.
2. Accordingly, Claims 29-37 are pending and will be examined on the merits.

Claim Rejections Maintained - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of Claims 29-32, 34, and 36-37 under 35 U.S.C. 102 (b) as being anticipated by Yue et al. (WO/2002/026982, published April 4, 2002, cited on IDS filed 07/17/2006) are maintained for the reasons of record.
5. The claims are drawn to a method of diagnosing cancer by detecting C20orf102 protein, which is secreted outside a cell, using an antibody recognizing C20orf102 protein in a sample from a subject. The C20orf102 protein is described in the specification as protein sequence SEQ ID NO:66 and gene sequence SEQ ID NO:2 (see Specification p. 50, 1st paragraph and Table 1, p. 73, No. TEG1).
6. Yue et al. teach a method of diagnosing cell proliferative disorders (e.g. cancers) by detecting nucleic acid and amino acid sequences of secreted proteins. Yue et al. disclose "the invention is based on the discovery of new human secreted proteins (SECP), the polynucleotides encoding SECP, and the use of these compositions for the

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diagnosis, treatment or prevention of cell proliferative, autoimmune/inflammatory, cardiovascular, neurological, and developmental disorders” (see p. 31, lines 28-31).

Yue et al. disclose the gene sequence for C20orf102 (SEQ ID NO:2 of the instant application) and the amino acid sequence for C20orf102 protein (SEQ ID NO:66 of the instant application) (see attached alignment). Claim 30 of Yue et al. teach a diagnostic assay comprising combining a biological sample with an antibody which specifically binds to a SECP polypeptide and detecting the complex, wherein the presence of the complex correlates with the presence of the SECP polypeptide in the biological sample (see also p. 59, lines 5-6). Yue et al. disclose “sequences encoding SECP may be used for the diagnosis of disorders associated with expression of SECP” (see p. 60 lines 10-11). Yue et al. disclose several cancers including liver, lung, and pancreas (see p. 60-61). Yue et al. teaches each and every limitation of the claims.

Response to Arguments

7. Applicants' argue that the Yue et al. reference discloses 67 molecules which are useful in treatment of more than 220 diseases and lists more than 14,740 combinations of molecules and diseases in total. Applicants argue that Yue et al. only discloses a genus invention in a comprehensive manner but fails to provide sufficiently specified or described combinations of the species invention as claimed in the instant application. Applicants' further argue that SEQ ID NO: 3 of Yue et al. shows a local homology of 51% with a mouse transmembrane protein and does not mention a possible relationship between the specific gene and any type of cancer. These arguments have been carefully considered but not found persuasive.

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8. As stated in the rejection above, Yue et al. teach the only active step claimed which is collecting a sample from a subject and detecting human C20orf102 protein in said sample. Although, Yue et al. teach a number of diseases and associated genes, the instant claims do not limit the patient population or sample population and therefore read on a very broad population. An alignment was also provided in the office action mailed 11/19/2008 which showed 100% homology to the human C20orf102 protein (SEQ ID NO: 66) described in the instant application with the sequence disclosed in Yue et al. Therefore, the reference teaches each and every limitation of the claims. The rejection of record is maintained.

Claim Rejections Maintained - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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11. The rejection of Claims 29-37 under 35 U.S.C. 103(a) as being unpatentable over Yue et al. (WO/2002/026982, published April 4, 2002, cited on IDS filed 07/17/2006) in view of Ruben et al. (US Patent 7169565) are maintained for the reasons of record.

12. The claims are drawn to a method of diagnosing cancer by detecting C20orf102 protein, which is secreted outside a cell, using an antibody recognizing C20orf102 protein in a blood, serum, or plasma sample from a subject. The C20orf102 protein is described in the specification as amino acid sequence SEQ ID NO:66 and gene sequence SEQ ID NO:2 (see Specification p. 50, 1st paragraph and Table 1, p. 73, No. TEG1).

13. The teachings of Yue et al. are presented in the 102(b) rejection set forth above. Yue et al. does not teach a sample from a subject comprising blood, serum or plasma.

14. Ruben et al. teach a method of identifying polypeptides in a biological sample for the diagnosis of diseases using antibodies directed to said polypeptide. Ruben et al. disclose detecting expression levels of said polypeptides in bodily fluids such as blood serum or plasma (see column 30, lines 48-54).

15. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method taught by Yue et al. of determining the presence of C20orf102 protein using an antibody in samples such as blood, plasma or serum from a subject as taught by Ruben et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Yue et al. and Ruben et al. because Yue et al. disclose bodily

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fluids can be used in the method of detecting C20orf102 protein and Ruben et al. disclose bodily fluids such as blood, plasma and serum can be used in a method to detect polypeptide levels using an antibody directed to said polypeptide. Therefore, Claims 29-37 are obvious over Yue et al. in view of Ruben et al.

Response to Arguments

16. Applicants' argue in view of the inherent nature of the molecule described in the Yue et al. reference, there is no reason for a person of skill in the art to combine the C20orf102 protein anchored on the cell surface as disclosed in the Yue et al. reference with a method for detection of a molecule in blood, plasma or serum as described in Ruben et al. This argument has been carefully considered but not found persuasive.

17. The molecules disclosed in Yue et al. are human secreted proteins (SCEP) and therefore would be found in bodily fluids such as blood, plasma, or serum. As sated in the 103(a) rejection in the office action mailed 11/19/2008, Ruben et al. disclose bodily fluids such as blood, plasma and serum can be used in a method to detect polypeptide levels using an antibody directed to said polypeptide. The rejection of record is therefore maintained.

All other rejections are withdrawn in view of Applicants amendments to the claims in the response filed 04/13/2009.

Conclusion

18. Claims 29-37 are rejected.

19. No Claim is allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643